

Food and Drug Administration, HHS

§ 600.20

Form FDA-3486 to the Director, Office of Compliance and Biologics Quality (HFM-600), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, by either a paper or an electronic filing:

(1) If you make a paper filing, you should identify on the envelope that a BPDR (biological product deviation report) is enclosed; or

(2) If you make an electronic filing, you may submit the completed Form FDA-3486 electronically through CBER's website at www.fda.gov/cber.

(f) *How does this regulation affect other FDA regulations?* This part supplements and does not supersede other provisions of the regulations in this chapter. All biological product deviations, whether or not they are required to be reported under this section, should be investigated in accordance with the applicable provisions of parts 211 and 820 of this chapter.

[65 FR 66634, Nov. 7, 2000]

§ 600.15 Temperatures during shipment.

The following products shall be maintained during shipment at the specified temperatures:

(a) *Products.*

Product	Temperature
Cryoprecipitated AHF	– 18 °C or colder.
Measles and Rubella Virus Vaccine Live.	10 °C or colder.
Measles Live and Smallpox Vaccine.	Do.
Measles, Mumps, and Rubella Virus Vaccine Live.	Do.
Measles and Mumps Virus Vaccine Live.	Do.
Measles Virus Vaccine Live ..	Do.
Mumps Virus Vaccine Live	Do.
Fresh Frozen Plasma	– 18 °C or colder.
Liquid Plasma	1 to 10 °C.
Plasma	– 18 °C or colder.
Platelet Rich Plasma	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 and 24 °C, if the label indicates storage between 20 and 24 °C.

Product	Temperature
Platelets	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 to 24 °C, if the label indicates storage between 20 and 24 °C.
Poliovirus Vaccine Live Oral Trivalent.	0 °C or colder.
Poliovirus Vaccine Live Oral Type I.	Do.
Poliovirus Vaccine Live Oral Type II.	Do.
Poliovirus Vaccine Live Oral Type III.	Do.
Red Blood Cells (liquid product).	Between 1 and 10 °C.
Red Blood Cells Frozen	– 65 °C or colder.
Rubella and Mumps Virus Vaccine Live.	10 °C or colder.
Rubella Virus Vaccine Live ...	Do.
Smallpox Vaccine (Liquid Product).	0 °C or colder.
Source Plasma	– 5 °C or colder.
Source Plasma Liquid	10 °C or colder.
Whole Blood	Blood that is transported from the collecting facility to the processing facility shall be transported in an environment capable of continuously cooling the blood toward a temperature range of 1 to 10 °C, or at a temperature as close as possible to 20 to 24 °C for a period not to exceed 6 hours. Blood transported from the storage facility shall be placed in an appropriate environment to maintain a temperature range between 1 to 10 °C during shipment.
Yellow Fever Vaccine	0 °C or colder.

(b) *Exemptions.* Exemptions or modifications shall be made only upon written approval, in the form of a supplement to the biologics license application, approved by the Director, Center for Biologics Evaluation and Research.

[39 FR 39872, Nov. 12, 1974, as amended at 49 FR 23833, June 8, 1984; 50 FR 4133, Jan. 29, 1985; 50 FR 9000, Mar. 6, 1985; 55 FR 11013, Mar. 26, 1990; 59 FR 49351, Sept. 28, 1994; 64 FR 56449, Oct. 20, 1999]

Subpart C—Establishment Inspection

§ 600.20 Inspectors.

Inspections shall be made by an officer of the Food and Drug Administration having special knowledge of the